

National Cancer Institute
Institutional Review Board

AGENDA
August 24, 2015
1:00 – 5:00 pm
10 CRC/3-1608

- 1. Review of Draft Minutes, August 10, 2015**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Response to Stips** P142104, "A Randomized, Double-blind, Placebo-controlled Study of the Safety and Efficacy of Amatuximab in Combination with Pemetrexed and Cisplatin in Subjects with Unresectable Malignant Pleural Mesothelioma"—Raffit Hassan, PI
- 9. Response to Stips** P152254, "Safety and Efficacy of Emtricitabine/Tenofovir Alafenamide as Part of Salvage Antiretroviral Regimens in Patients with Uncontrolled Viremia and Drug-Resistant HIV Infection"—Alice Pau, PI
- 10. Amendment** 13C0105-H, "Molecular Profiling-based Assignment of Cancer Therapy for Patients with Advanced Solid Tumors"—Alice Chen, PI
- 11. Amendment** 15C0086-C, "Phase I Trial of the Combination of Nilotinib and Paclitaxel in Adults with Refractory Solid Tumors"—Alice Chen, PI
- 12. Amendment** 14C0184-B, "Phase I Study of the Safety and Tolerability of ATR-101 in Adrenocortical Carcinoma"—Electron Kebebew, PI
- 13. Amendment** 12C0136-B, "A Phase II Randomized Trial of Lenalidomide (NSC #703813, IND #70116) in Pediatric Patients with Recurrent, Refractory, or Progressive Juvenile Pilocytic Astrocytomas and Optic Pathway Gliomas"—Kathy Warren, PI
- 14. Amendment** 14C0079-B, "An Exploratory Study of Voicing My CHOICES as a Tool for Advanced Care Planning in Young Adults with Metastatic, Recurrent, or Progressive Cancer"—Lori Wiener, PI